

Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

1. (Currently amended) A freeze-dried preparation comprising methylcobalamin or a pharmacologically acceptable salt thereof and an excipient,

wherein said excipient comprises at least one sugar or sugar alcohol, said sugar being selected from the group consisting of glucose, fructose, maltose, lactose, sucrose and trehalose, and said sugar alcohol being selected from the group consisting of inositol, sorbitol and mannitol, wherein at least one or more of said sugar or said sugar alcohol in said species of the excipient is in an amorphous state, and said sugar or said sugar alcohol that is present in said amorphous state is present in said excipient in an amount that is at least 20% by weight, based on the total weight of said excipient.

2. (Previously presented) The freeze-dried preparation according to claim 1, wherein the methylcobalamin or the pharmacologically acceptable salt thereof is also in an amorphous state.

3. - 4. (Canceled)

5. (Currently amended) The freeze-dried preparation according to claim 1 or claim 2, further comprising a pH adjuster.

6. (Currently amended) The freeze-dried preparation according to claim 1 or claim 2, further comprising an anti-oxidant.

7. (Currently amended) The freeze-dried preparation according to claim 1, wherein ~~when~~ the excipient comprises at least one of both said the sugar and said the sugar alcohol, ~~the excipient in the amorphous state is contained in an amount of at least 20% by weight, based on the total weight of the sugar and the sugar alcohol.~~

8. (Currently amended)) A freeze-dried preparation comprising methylcobalamin or a pharmacologically acceptable salt thereof and an excipient, the freeze-dried preparation obtained by a production process which comprises the steps of:

(a) dissolving the methylcobalamin or the pharmacologically acceptable salt thereof and the excipient in a solvent, wherein said excipient comprises at least one sugar or sugar alcohol, said sugar being selected from the group consisting of glucose, fructose, maltose, lactose, sucrose and trehalose, and said sugar alcohol being selected from the group consisting of inositol, sorbitol and mannitol; and

(b) freeze-drying the solution so as to produce an amorphous state of at least one or more of said sugar or of said sugar alcohol in said species of the excipient wherein said sugar or said sugar alcohol that is in said amorphous state is present in said excipient in an amount that is at least 20% by weight, based on the total weight of said excipient.

9. (Previously presented) The freeze-dried preparation according to claim 8, wherein the freeze-drying in the step (b) is accomplished so as to further produce an

amorphous state of the methylcobalamin or the pharmacologically acceptable salt thereof.

10. (Currently amended) The freeze-dried preparation according to claim 8 or claim 9, wherein ~~[[the]]~~ pre-freezing during said freeze-drying process in ~~[[the]]~~ step (b) is performed at a temperature at which the excipient does not crystallize, or below the temperature.

11. - 12. (Canceled)

13. (Currently amended) The freeze-dried preparation according to claim 8 or claim 9, wherein a pH adjuster is also dissolved in ~~[[the]]~~ step (a).

14. (Currently amended) The freeze-dried preparation according to claim 8 or claim 9, wherein an anti-oxidant is also dissolved in ~~[[the]]~~ step (a).

15. (Currently Amended) The freeze-dried preparation according to claim 8 or claim 9, wherein ~~when~~ the excipient comprises at least one of both said the sugar and said the sugar alcohol, ~~the excipient in the amorphous state is contained in an amount of at least 20% by weight, based on the total weight of the sugar and the sugar alcohol.~~

16. (Withdrawn-currently amended) A process for producing a freeze-dried preparation comprising methylcobalamin which comprises the steps of:

- (1) dissolving the methylcobalamin or a pharmacologically acceptable salt thereof and an excipient in a solvent, wherein said excipient comprises at least one sugar or sugar alcohol, said sugar being selected from the group consisting of glucose, fructose, maltose, lactose, sucrose and trehalose, and said sugar alcohol being selected from the group consisting of inositol, sorbitol and mannitol; and
- (2) freeze-drying the solution so as to produce an amorphous state of at least one or more of said sugar or of said sugar alcohol in said ~~species of the~~ excipient wherein said sugar or said sugar alcohol that is in said amorphous state in said excipient is present in said excipient in an amount that is at least 20% by weight, based on the total weight of said excipient.

17. (Withdrawn-currently amended) The process according to claim 16, wherein the freeze drying in ~~[[the]]~~ step (2) is performed so as to further produce an amorphous state of the methylcobalamin or the pharmacologically acceptable salt thereof.

18. (Withdrawn-currently amended) The process according to claim 16, wherein ~~[[the]]~~ pre-freezing during said freeze-drying process in ~~[[the]]~~ step (2) is performed at a temperature at which the excipient does not crystallize, or below the temperature.

19.-20. (Canceled)

21. (Withdrawn) The process according to claim 16, wherein the freeze-dried preparation further comprises a pH adjuster.

22. (Withdrawn) The process according to claim 16, wherein the freeze-dried preparation further comprises an anti-oxidant.

23. (Withdrawn-currently amended) The process according to claim 16, wherein ~~when the excipient comprises~~ both said ~~[[the]]~~ sugar and said ~~[[the]]~~ sugar alcohol, ~~the excipient in the amorphous state is contained in an amount of at least 20% by weight, based on the total weight of the sugar and the sugar alcohol.~~

24. (New) The freeze-dried preparation according to claim 5, further comprising an anti-oxidant.

25 (New) The freeze-dried preparation according to claim 10, wherein a pH adjuster is also dissolved in step (a).

26 (New) The freeze-dried preparation according to claim 10, wherein an anti-oxidant is also dissolved in step (a).

27 (New) The freeze-dried preparation according to claim 13, wherein an anti-oxidant is also dissolved in step (a).